K022163

SEP 17 2002

V. 510(k) Summary

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Contact Person: David Klementowski
Corporate Regulatory Affairs Manager

Date Prepared: 20 May 2002

Proprietary Name: Welch Allyn Spot Vital Sign Monitor with MP506

Common Name: Vital Signs measurement device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure Measurement System

Predicate Devices: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530*

OxiMax Pulse Oximetry System w/N-595 Pulse Oximeter
Nellcor Puritan Bennett, Incorporated
510(k) Document Control Number *K012891*

Description of the Device:

The Welch Allyn Spot Vital Signs is not a monitor, but a one-time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals, memory, or any various programmable alarm features. The device is intended to provide the physician, physician's assistant, or nurse, facing high patient traffic or multiple tasks, a cost effective method to determine a one-time vital signs reading on the spot. The base unit will have non-invasive blood pressure (BP) measurement. Options will also be offered such as SureTemp® thermometry, Nellcor® pulse oximetry (SpO_2), mounting bracket, and rolling stand. The device may be interfaced with an external printer via an infrared port.

The Welch Allyn Spot Vital Signs is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO2) for adult and pediatric patients. The Welch Allyn Spot Vital Signs also calculates Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature and SpO2 values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Spot Vital Signs convenient for many locations.

Intended Use

The Welch Allyn Spot Check Device Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece Cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.

The Welch Allyn Spot Check Device is not intended to monitor patient's vital signs.

The Welch Allyn Spot Check Device is not defibrillator proof.

Action Taken to Comply with Section 514 of the Act

The agency has recognized the following standards:

a) EN60601-1
b) EN60601-1-1
c) EN60601-1-2
d) EN60601-1-4
e) AAMI SP10
f) ASTM 1112-86
g) EN 865

The Welch Allyn Spot Vital Sign with MP506 Pulse Oximeter OEM module meets the requirements called out in these standards. Evidence of compliance is on file at Welch Allyn and is available for review upon demand.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

Mr. David Klementowski
Corporate Regulatory Affairs Manager
Welch Allyn, Incorporated
4341 State Street Road
Skaneateles Falls, New York 13153-0220

Re: K022163
Trade/Device Name: Welch Allyn Spot Vital Sign Monitor with MP506
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 13, 2002
Received: August 20, 2002

Dear Mr. Klementowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use Statement

510(k) Number: Unknown K022163

Device Name: Welch Allyn Spot Vital Signs

Indications for use: The Welch Allyn Spot Vital Signs is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

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(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K022163